Martin, Ingrid

From: Liner, Susan E <Susan.Liner@fda.hhs.gov>
Sent: Wednesday, July 10, 2013 8:37 AM
To: Martin, Ingrid
Cc: Archdeacon, Karen N; Wardwell, Amber
Subject: RE: Ameridose & Alaunus: Disposal and Return of Product

Ingrid

The details for the disposition are for DEA regulated products and your firm should proceed as directed in the letter response from DEA.

The question remains disposition for **non DEA Products (not controlled)**.

We will need a description of current inventory and plans for the disposal (Company name, method of destruction, site of destruction and date proposed).

Once the destruction date is established , FDA investigators will examine and confirm the inventory and witness the destruction .

The firm will need to provide a Voluntary Destruction Statement on the firm's letterhead, per the following.

1. Voluntary nature of the action.
2. Name of the product, including applicable code marks.
3. Condition of the lot.
4. Amount.
5. Method of destruction.
6. Signature of responsible individual

Regards,

Susan Liner
NWE-DO Recall Coordinator
Phone: 781-587-7481
Fax: 781-587-7556
Email: susan.liner@fda.hhs.gov
Please send all Recall Correspondence to: newenglandrecalls@fda.hhs.gov

From: Martin, Ingrid [mailto:imartin@collorallp.com]
Sent: Tuesday, July 09, 2013 4:26 PM
To: Liner, Susan E
Cc: Cirel, Paul; 'Yeager, Nathaniel (USAMA)'; 'nancy.dolberg@state.ma.us'
Subject: Ameridose & Alaunus: Disposal and Return of Product

Dear Ms. Liner:

In late June, I sent you letters outlining proposals by Alaunus and Ameridose for returning and/or disposing of products currently at the facilities. Copies of those letters are attached for your reference. I received a letter from the DEA today stating that they believe the proposed procedures are acceptable. A copy of that letter is attached as well. Please let me know at your earliest convenience if the FDA is of the same view as the DEA.

Thank you.

-- Ingrid Martin

Ingrid S. Martin

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